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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/801,906	03/16/2004	Anthony J. Melkent	5074A-000010/DVB	3395
27572 7590 07/06/2009 HARNESSE, DICKEY & PIERCE, P.L.C. P.O. BOX 828 BLOOMFIELD HILLS, MI 48303				
EXAMINER				
COLELLO, ERIN L				
ART UNIT		PAPER NUMBER		
3734				
MAIL DATE		DELIVERY MODE		
07/06/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/801,906

Applicant(s)

MELKENT ET AL.

Examiner

ERIN COLELLO

Art Unit

3734

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-17, 19,39-45 and 47-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-17, 19,39-45 and 47-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 March 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This Office Action is in response to the Request for Continued Examination filed on April 21, 2009. Claims 1, 3-17, 19, 39-45 and 47-52 and new claims 53-54 will be prosecuted on the merits.

Applicant's arguments with respect to claim 1, 3-17, 19, 39-45 and 47-52 have been considered but are moot in view of the new ground of rejection.

Drawings

1. The previous acceptance of the drawing was in error and the drawings are objected to because the drawings must show every feature of the invention specified in the claims. Therefore, the dovetail connector and the adjustable cannulas must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an

application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 315a, b, c; 305 and 317. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 6, 7, 8, 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 6-8 state, "at least one of the plurality of cannulas is individually adjustable to vary its angular position" which is vague and indefinite because it is not fully understood how the "cannula is individually adjustable to vary its angular position" and the specification does not provide guidance as to how the "cannula is individually adjustable to vary its angular position". Correction is needed.

5. Furthermore, it is noted that any attempt to clarify the how the "cannula is individually adjusted to vary its angular position" may introduce new matter.

Claim 11 states, "the peripheral structure is machine operated means" which is vague and indefinite because it is not fully understood how "the peripheral structure is machine operated means" and the specification does not provide guidance as to how the "the peripheral structure is machine operated means". Correction is needed.

6. Furthermore, it is noted that any attempt to clarify the how the "the peripheral structure is machine operated means" may introduce new matter

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1, 3-10, 12-13, 17, 19, 39-45, 47-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Hynes et al. (US 6,117,143)** in view of **Cosman (US 6,675,040 B1)** and **Foley et al. (US 6,226,548 B1)**.

Regarding claims 1, 3-4, 9-10, 12-13, 19, 39-40, 45, 47-54, Hynes discloses an apparatus for the placement of surgical implements, comprising: a fixture that defines a plurality of attachment points that are fixed relative to each other (Ref 56; wherein the openings are fixed relative to each other); a plurality of cannulas coupled to a fixture with each of the plurality of cannulas coupled to a respective one of the plurality of attachment points and are independently adjustable relative to the fixture (Ref 80; Column 6, Lines 34-47); wherein the fixture is interchangeable insofar as it is configured to accommodate at least one of: a variable number of cannulas, a plurality of cannulas having a plurality of placements relative to the fixture, or a plurality of cannulas having a plurality of fixed relative angles ; wherein the cannulas can be fixed parallel to one another (Ref 80; Column 6, Lines 34-47); a peripheral structure in the form of a graspable portion handle so that manipulation of the handle maneuvers the plurality of cannulas simultaneously during a surgical procedure to place the surgical implements (Ref 38, 48, 58); at least one trackable marker associated with the plurality of cannulas (Ref 94; Column 6, Lines 60-67); and a plurality of surgical implement receivers provided on the fixture for receiving surgical implements; wherein the receiver is a flange configured to receive the surgical implements (Ref 74, 70), at least one of the plurality of receivers being substantially coaxially aligned with a respective one of the plurality of cannulas to enable a surgical implement to pass through a respective one of

the plurality of receivers and a respective one of the plurality of cannulas (Ref 74, 70, 80, 106, 90), wherein the surgical implement is at least one of a surgical tool or an implant (Ref 90, 106, Column 7, Lines 16-21); a second fixture different from the first fixture and having a second configuration defined by a plurality of attachment points that are fixed relative to each other (Column 8, Lines 13-19; wherein the additional assembly (54) is the second fixture), and the at least one trackable marker is detectable by an instrument location system to detect the position of the plurality of cannulas relative to an anatomy in real-time (column 6, Lines 60-67; Column 7, lines 1-15); a surgical navigation system that tracks the plurality of trackable markers to determine a position of each of the plurality of cannulas relative to an anatomy (column 6, Lines 60-67; Column 7, lines 1-15); an imaging device operable to acquire one or more images of the anatomy (column 6, Lines 60-67; Column 7, lines 1-15); and a display that displays an icon representative of the position of each of the plurality of cannulas superimposed onto an image of the anatomy, wherein the display also displays a plurality of icons that each represent a projected trajectory for each of the plurality of cannulas superimposed onto the image of the anatomy (Ref 100; column 6, Lines 60-67; Column 7, lines 1-15).

Hynes discloses all of the claimed limitations above but fails to explicitly disclose that the trackable marker is mounted on a frame that is coupled to a fixture and fails to disclose that a plurality of interchangeable frames, at least two of the frames having a different type of trackable marker and that the frame is removably coupled relative to the fixture using a dove-tail connection.

However, Cosman teaches that it is well known in the art for a frame with trackable markers mounted thereon to be coupled to a surgical instrument, a patient, a surgeon or any part of the surgical field; wherein the frame can be interchanged with another frame having a different type of trackable marker (Figures 2A-4C; Column 7, Lines 9-31; Column 8, Lines 20-31 and 48-67; Column 9, Lines 1-9; Column 10, Lines 1-17)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the marker of Hynes to be removably attached to a portion of the surgical field by means of frame as taught by Cosman, since such a modification allows different types of markers to be used in order to distinguish the different tools and device as well as allows the frames and markers to be sterilized.

Hynes as modified by Cosman discloses that the frames are removably connected to an instrument by means of a connector but fails to explicitly disclose that the connector is a dove-tail connector.

However, Foley teaches that it is well known when using a computer-assisted surgical navigation system to have a removably coupled frame relative to the fixture using a dove-tail connection (Figures 4D-F, (55), (56))

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the frame of Funda to include a removably couple frame as taught by Foley, since such a modification enhances the device by allowing the portions of the system to be removable in order to be sterilized.

Regarding claims 5 and 42, Hynes discloses that at least one of the plurality of cannulas is individually adjustable to vary its length (Ref 80; Column 6, Lines 34-47; wherein the length is adjusted by inserting the cannula to the desired length).

Regarding claims 6, 7, 8 and 43, Hynes discloses that at least one of the plurality of cannulas is individually adjustable to vary at least one of its angular positions; wherein the at least one angular position is an azimuth angular position measured in a horizontal reference plane associated with the fixture and an elevation angular position measured in a vertical reference plane associated with the fixture (Ref 80; Column 6, Lines 34-47).

Regarding claims 41, Hynes discloses that the second fixture is operable to enable at least one of the plurality of cannulas to be individually adjustable to vary its angular position relative to the second fixture (Column 6, Lines 34-47; Column 8, Lines 13-19).

Regarding claims 17 and 44, Hynes discloses that the at least one trackable marker is selected from a group comprising a reflective marker, a light emitting marker, an acoustic marker, a magnetic marker, an optical marker, an electromagnetic marker, a radiological marker, and combinations thereof (Column 6, lines 60-67; Column 7, Lines 1-15).

9. Claims 11 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Hynes et al. (US 6,117,143)** in view of **Cosman (US 6,675,040 B1)** and **Foley et al. (US 6,226,548 B1)** as applied to claim 1 above and further in view of **Funda et al. (5,572,999)**.

Regarding claim 11, Hynes discloses all of the claimed limitations above but fails to explicitly disclose that the peripheral structure is machine operated means.

However, Funda teaches that it is well known in the art that the peripheral structures can be machine operated or manually controlled by a surgeon (Figure 1, (242); Column 4, Lines 46-48).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the peripheral structure of Hynes to be machine operated as taught by Funda, since such a modification simplifies the procedure by allowing the control of the peripheral structure to be controlled by a computer.

Regarding claim 16, Hynes discloses all of the claimed limitations above but fails to explicitly disclose that at least one of the plurality of cannulas includes a serrated structure for gripping portions of a patient's anatomy.

However, Funda teaches that it is well known in the art that a cannulas can includes a surgical instrument such as forceps which contains a serrated structure for gripping portions of a patient's anatomy (Column 13, Lines 17-28).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the cannula of Hynes to include a serrated structure as taught by Funda, since such a modification enhances the device by allowing portions of the anatomy to be gripped or sampled.

10. Claims 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Hynes et al. (US 6,117,143)** in view of **Cosman (US 6,675,040 B1)** and **Foley et al. (US 6,226,548 B1)** as applied to claim 1 above.

Regarding claims 14-15, Hynes discloses all of the claimed limitations above but fails to explicitly disclose that at least one of the plurality of cannulas can be interchanged with a cannula having at least one of a different inner diameter or outer diameter or that the cannula is individually adjustable to vary at least one of its inner diameter or outer diameter

However, it would be obvious to one of ordinary skill in the art at the time the invention was made to have a cannula that can vary in diameter in order to allow different size instruments to enter the lumen.

Response to Arguments

Applicant's arguments with respect to claim 1, 3-17, 19, 39-45 and 47-52 have been considered but are moot in view of the new ground of rejection.

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 39, 42-43, 48-50-53 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8, 14, 16, 32, 33, 42-46, 50 of U.S. Patent No. 6,725,080. Although the conflicting claims are not identical, they are not patentably distinct from each other because the limitations of claims 39, 42-43, 48-50-53 can be found in claims 1-8, 14, 16, 32, 33, 42-46, 50 of Patent '080.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIN COLELLO whose telephone number is (571)270-3212. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kevin T. Truong/
Primary Examiner, Art Unit 3734

EC
Art Unit 3734